

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_# Pages Doc._Date Title

CDRH F-O-D Document Domain = DSMA

COMMITTEE/PANEL INFO.

1091	2	03/13/97	Opportunity to Provide Comments and Suggestions on 510(k) Process Reengineering
2001	1	04/19/95	Advisory Committee Information Line
2099	12	07/11/96	Telemedicine Related Activities
3099	9	09/09/96	Appendix A - Working Definition of Telehealth/Telemedicine Telemedicine Sub-group, Health Applications Working Group

COMPLIANCE POLICY GUIDES

020	59	04/01/87	Medical Device GMP Guidance for FDA Investigators FDA84-4191
038	3	03/01/84	Status and Responsibilities of Contract Sterilizers Engaged in the Sterilization of Drugs and Devices CPG 7150.16
039	6	12/30/87	CPG 7124.21 - Condom; Defect - Criteria for Direct Reference Seizure
040	2	04/16/87	CPG 7132a.15 - Computerized Drug Processing; Source Code for Process Control Application Programs
041	5	06/03/87	CPG 7150.10 Chapter 50 - General Policy Guide - Health Fraud - Factors in Considering Regulatory Action
042	1	09/24/87	Oxygen Equipment - Emergency and OTC Use CPG 7124.10
043	3	11/05/87	CPG 7132a.16 - Compressed Medical Gases - Direct Reference Authority for Sending Regulatory Letters for Specific CGMP Deviations
044	3	09/08/88	Blood Pressure Measurement Devices (Sphygmomanometers) - Accuracy CPG 7124.23
045	1	08/09/88	Status of Dental Supplies such as Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic CPG 7124.05
046	2	11/21/88	Electrical Muscle Stimulators (EMS) :CPG 7124.26
048	2	09/24/87	Reuse of Medical Disposable Devices: CPG 7124.16
049	3	10/19/90	Class III Devices Subject to 515(b) Requirements: CPG 7124.18
050	3	02/26/91	Direct Reference Authority for Class III Medical Devices without a Premarket Notification [510(k)] or an Approved Premarket Approval Application (PMA) CPG 7124.30
057	26	10/20/89	CPG 7382.004 - Field Compliance Testing of Cabinet X-Ray Equipment
058	53	06/06/89	CPG 7348.809 - Institutional Review Board
059	32	06/06/89	CPG 7348.808 - Good Laboratory Practice (Nonclinical

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Laboratories)
060	32	09/01/91	CPG 7348.811 - Clinical Investigators
062	1	01/03/96	CPG 7151.02 FDA Access to Results of Quality Assurance Program Audits and Inspections
063	68	07/26/96	CPG 7382.830A - Sterilization of Medical Devices
064	48	10/01/88	CPG 7382.830B - Contract Sterilizers
073	25	12/31/91	CPG 7348.810 - Sponsors, Contract Research Organizations and Monitors
075	5	05/15/90	CPG 7382.002 - Field Implementation of the Sunlamp and Sunlamp Product Performance Standard as Amended -- Attachment B and B.1
195	8	03/03/97	CPG 7150.01, Certification for Exports - Sec. 110.100
204	32	01/13/95	Procedures for Obtaining FDA Approval to Export Unapproved Medical Devices
493	5	07/01/91	CPG 7150.09 Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities
534	12	10/01/91	CPG 7382.008 - Monitoring Devices of Foreign Origin - Imports
825	23	02/12/96	CPG 7383.003 510(K) Premarket Approval Inspections

COMPLIANCE\LETTERS

826	7	02/12/96	Device Industry Letter: Enforcement Activities/Policy/Discussion of the Reference List
865	19	10/01/96	The FDA Export Reform and Enhancement Act of 1996 / Export Certification
961	3	02/12/96	Letter: Re-Use of Single-Use or Disposable Medical Devices

COMPLIANCE\OTHER

012	11	07/17/95	Draft Instructions for Medical Device Listing
021	11	05/01/87	Medical Device Establishment Registration Information and Instructions
125	19	05/23/91	FDA Regulatory Procedures Manual Chapter 8-10 Warning Letters
293	14	04/08/87	Condoms: Inspection and Sampling at Domestic Manufacturers and of all Repackers; Sampling from all Importers
492	11	06/01/91	Points to Consider for Internal Reviews and Corrective Action Operating Plans
508	27	07/24/96	A Pocket Guide to Device GMP Inspections - Inspections of Medical Device Manufacturers and GMP Regulation
586	10	01/28/92	Regulatory Procedures Manual Chapter 9-87 - Priority Enforcement Strategy for Problem Importers
796	9	07/01/94	Inspections of Foreign Device Manufacturers

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
868	30	02/01/89	Compressed Medical Gases Guideline
874	2	02/07/96	Kit Certification and Information for Kit 510(k)s
918	33	01/10/94	Guideline for the Manufacturer of In Vitro Diagnostic Products
977	8	03/01/96	A Guide for the Submission of Abbreviated Radiation Safety Reports on Cephalometric Devices
978	7	03/01/96	A Guide for the Submission of An Abbreviated Radiation Safety Report on X-ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use
979	6	03/01/96	A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammographic X-ray Systems

COMPLIANCE\PROGRAMS

2702	50	05/01/95	CPG7382.830 Inspection Med/Dev. Manuf.
3702	39	05/01/95	CPG7382.830 Attach. A, GMP Inspections (unchanged)
4702	38	05/01/95	CPG7382.830, Attachment A-1, Process for Compliance Review of Class I & II 510(k) Submissions/PMA Supplements Submission Review
5702	75	05/01/95	CPG 7382.830 Atts B, C, D, E, & F
6702	32	05/01/95	CPG 7382.830 Att G, Model Warning letter
7702	4	05/10/95	CPG7382.830 April 7, 1995 Letter
839	2	09/15/95	Additional FDA Recommendations to the GMP Advisory Committee

COMPLIANCE\TRACKING

875	21	02/07/96	Device Tracking Questions and Answers Based on the Final Rule
-----	----	----------	---

DEVICE CATEGORIES

017	7	01/01/87	Classifying Your Medical Devices FDA87-4223
-----	---	----------	---

DSMA WORKSHOP SCHEDULE

140	1	03/19/97	DSMA Workshop Schedule FY'97
-----	---	----------	------------------------------

EVALUATION GUIDANCE

952	17	02/07/97	Draft: A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems
-----	----	----------	--

INSTRUCTIONS & INDEXES

000	1	04/30/96	CDRH Facts-On-Demand (F-O-D) Instruction Page
299	1	09/25/91	How to Order Publications (from non-DSMA sources)
3913	63	04/09/97	DSMADOC.ALL, sorted by Title

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
3919	20	11/19/96	Complete CDRH F-O-D Index
486	3	03/15/96	Division of Small Manufacturers Assistance Publication Order Form (DSMA Order Form)
4913	63	04/09/97	DSMADOC.ONE, sorted by Shelf_#
5913	63	04/09/97	DSMADOC.DAT, sorted by Doc._Date
6913	63	04/09/97	DSMADOC.LOG, sorted by Login_Date
7799	1	03/11/96	Access to Complete DSMA Facts index from WWW
7800	1	06/05/96	DSMA Facts Category Index
7801	2	03/21/96	Center & Office Director Letters
7802	1	03/21/96	Committe/Panel Info.
7803	1	03/21/96	Compliance\Letters
7804	1	03/21/96	Compliance\Policy Guides
7805	1	03/21/96	Compliance\Programs
7806	1	03/21/96	Compliance\Other
7807	1	03/21/96	Compliance\Tracking
7808	2	03/21/96	Instructions & Indexes
7809	1	03/21/96	Manufacturer Assistance\General
7810	1	03/21/96	MDR Policies\Guidelines
7811	2	03/21/96	Medwatch Information
7812	2	03/21/96	ODE\Blue Book
7813	1	03/21/96	ODE\DCLD\ GUIDANCE
7814	2	03/21/96	ODE\DCRND\ GUIDANCE
7815	2	03/21/96	ODE\DGRD\ GUIDANCE
7816	1	03/21/96	ODE\DOD\ GUIDANCE
7817	2	03/21/96	ODE\DRAERD\ GUIDANCE
7818	2	03/21/96	ODE\OTHER\ GUIDANCE
7819	1	03/21/96	POSTMARKET SURVEILLANCE\OTHER
7820	1	03/21/96	RADIOLOGICAL HEALTH - LASERS
7821	1	03/21/96	RADIOLOGICAL HEALTH - MICROWAVE
7822	1	03/21/96	RADIOLOGICAL HEALTH - NON-IONIZING
7823	1	03/21/96	RADIOLOGICAL HEALTH - OTHER
7824	1	03/21/96	RADIOLOGICAL HEALTH - SUNLAMPS
7825	1	03/21/96	RADIOLOGICAL HEALTH - TELEVISION
7826	1	03/21/96	RADIOLOGICAL HEALTH - ULTRASONIC
7827	1	03/21/96	PUBLIC INFORMATION\OTHER
7828	1	03/21/96	REGULATIONS\CFR PARTS
7829	1	03/21/96	REGULATIONS\OTHER
7830	1	03/21/96	REGULATIONS\FOREIGN
7831	1	03/21/96	REGULATIONS\UNCODIFIED

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
7832	1	03/21/96	SAFETY ALERTS
7833	2	03/21/96	WORKSHOPS
919	1	09/19/96	DSMA Facts Index Categories (CDRH Facts-On-Demand)
LETTERS\CENTER & OFFICE DIRECTOR			
056	2	04/05/94	Letter - Condom Manufacturers and Distributors: Re: Air Burst Test on Condom Products
168	16	03/21/97	Increasing the Effectiveness of FDA's Medical Device Program: a Risk Based Approach
170	13	11/17/95	Citizen's Petition, Docket No. 95P-0110, Response by William B Schultz
345	2	05/31/96	Revised Medical Device Reporting (MDR) Letter
457	10	04/16/90	Radiation Exposure From Medical Imaging Demonstrations: To Manufacturers of Imaging Devices, Officials for Major Medical Meetings, Professional Medical Organizations
589	1	09/28/92	Denter Handpiece Sterilization Letter-
601	14	11/01/95	Burlington Letter: President/CEO - Progress in the Premarket Review Program
639	2	06/13/95	Memorandum Electromagnetic Compatibility for Medical Devices: Issues and Solutions
941	7	05/18/95	Letter to President/CEO from Burlington on Status of 510(k) Submissions
LETTERS\OTHER			
458	2	05/01/91	Letter - To All Manufacturers of Latex Devices
522	2	06/12/91	Letter - Recodification of the Radiation Control for Health and Safety Act - To All Manufacturers and Importers of Electronic Products, Trade Associations, Radiological Health Personnel
545	2	05/17/93	Letter - Endoscopy and Laparoscopy Accessories - To Medical Device Industry
552	2	06/08/92	Letter - Second Tracking Regulation Transmittal Letter and Proposed List of Devices Subject to Tracking
585	6	01/17/92	Compliance Safe Medical Devices Act Letter
MANUFACTURER ASSISTANCE			
967	1	01/29/97	Division of Small Manufacturers Assistance Contacts/Services
MANUFACTURER ASSISTANCE\GENERAL			
009	38	08/01/92	Everything You Always Wanted to Know About Medical Device Requirements . . . and Weren't Afraid to Ask
434	2	01/01/87	Have a New Medical Device? Please Notify Us!
540	11	03/03/87	Special DSMA Report - Pertinent Voluntary Standards and

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
			Problem Definition Studies for Certain Pre-Amendment Class III Medical Devices
555	4	07/30/96	List of Current CDRH Addresses for Report Submission and Ordering of CDRH Forms
570	13	03/21/97	Sterilization: Questions and Answers
MDR POLICIES\ GUIDELINES			
1059	3	07/26/96	Variance from Manufacturer report Number Fromat Letter dated 7/16/96
1060	1	08/12/96	8/12/96 Variance 5 from Manufacturer Report Number Format
1061	5	07/19/96	Instrucxtions for Completing Form 3417: Medical Device Reporting Baseline Report
1074	2	07/24/96	Federal Register: Medical Devices; reporting; Certification and U.S. Designated Agents
1075	5	07/24/96	Federal Register: Medical Devices; Medical Device Distributor and Manufacturer Reporting; Certification, Registration, Listing, and Premarket Notification Submission; Stay of Effective Datre; Revocation of Final Rule
1094	1	09/24/96	Medical Device Reporting (MDR) Internet List Server (how to subscribe)
1095	1	10/03/96	FDA Workshop on Methods to Estimate Medical Device Denominator Data
1096	2	08/16/96	Federal Register: Medical Devices; Medical Device reporting; Baseline Reports; Stay of Effective Date
1097	3	08/16/96	MDR Guidance Document: Remedial Action Exemption - E1996001
1098	17	11/25/96	Medical Device reporting - Interim Compliance Program 7382.830 - Attachment E
1409	2	10/23/96	Instructions for completeting From 3419
1509	9	04/01/96	Graphs for: "Medical Device Reporting: An OVerview"
1799	1	10/29/96	World Wide Web (Internet)
188	3	06/12/95	MDR Guidance Document No. 2 - Remedial Action Exception
1987	7	05/06/96	Tables for: "Medical Device Reporting for Manufacturers"
1988	6	05/06/96	Tables for: "Medical Device Reporting for Distributors"
1989	5	05/06/96	Tables for: "Medical Device Reporting for User Facilities"
216	4	04/03/97	MDR Guidance Document No. 1 - Intraocular Lenses (IOL)
250	3	04/03/97	MDR Guidance Document No. 3 - Needlesticks and Blood Exposure
2799	1	10/29/96	CDRH Electronic Docket (ED)
336	30	05/08/96	Federal Register, Final Rule:Medical Devices; Medical Device User Facility and Manufacturer Reporting, Certification and

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
			Registration (Docket 91N-0295)
3799	7	12/12/96	NTIS
407	2	04/22/96	Medical Device Reporting - Baseline Report
409	2	04/22/96	Medical Device Reporting - Semi-Annual User Facility Report
452	4	04/03/97	MDR Reporting Guidance for Breast Implants
4799	3	10/29/96	Health Care & Industry Organizations
509	23	06/28/96	Medical Device Reporting: An Overview
5799	2	10/29/96	CDRH Facts-On-Demand (F-O-D)
973	1	05/01/96	Abbreviated Instructions for completing mandatory Medwatch Form 3500A
987	50	03/01/97	Medical Device Reporting for Manufacturers
988	28	04/01/96	Medical Device Reporting for Distributors
989	33	04/01/96	Medical Device Reporting for User Facilities

MEDWATCH INFORMATION

799	2	10/29/96	MDR Related Document Information
853	80	07/26/96	Instructions for Completing Form 3500A (Specific to Medical Device Reporting) With Coding Manual for Form 3500A - Med Watch MDR
854	2	12/15/95	MEDWATCH FDA Form 3500A; for use by User Facilities, Distributors and Manufacturers for Mandatory Reporting

ODE\BLUE BOOK

007	4	05/20/94	PMA/510(k) Expedited Review (#G94-2)
030	4	10/19/90	Consolidate Review of Submissions for Diagnostic Ultrasound Equipment & Related measurement Devices (#G90-2)
031	4	10/19/90	Consolidated Review of Submissions for Lasers and Accessories (#G90-1).
034	2	08/29/91	Review of Final Draft Medical Device Labeling (#P91-4)
035	2	08/29/91	Review of 510(k)s for Computer Controlled Medical Devices (#K91-1)
164	6	05/01/95	Blue Book: 95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"
1935	2	01/10/97	Blue Book Memo #K97-1 - Deciding When to Submit a 510(k) for a Change to an Existing Device
2106	9	09/15/95	Attachment A to #D95-2; Interagency Agreement
276	1	05/15/87	ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures - Blue Book Memo G87-2
280	1	07/01/86	Panel Review of "Me-Too" Devices
289	16	06/30/86	Guidance on the Center for Devices and Radiological Health's

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Premarket Notification Review Program
291	2	05/04/90	ODE Mentor Program (#A90-3)
292	3	05/18/90	Training Checklist for New Reviewers (#A90-4)
297	13	05/18/90	PMA Filing Decisions
301	2	07/25/86	Office of General Counsel (OCG) Review of PMA Summaries of Safety/Effectiveness
302	3	01/27/86	PMAs - Early Review and Preparation of Summaries of Safety and Effectiveness (#P86-1)
304	6	01/30/86	Criteria for Panel Review PMA Supplements
305	3	10/22/90	Review and Approval of PMAs of Licensees
306	7	04/18/86	Panel Report and Recommendations on PMA Approvals
308	4	06/03/94	510(k) Sign-off Procedures; Blue Book Memo K94-2
3106	1	09/15/95	Attachment B to #D95-2; Criteria for Categorization of Investigational Devices
328	2	10/16/86	Media Contacts (Blue Book #A86-1)
330	2	04/15/88	Review of Laser Submissions (Blue Book Memo #88-1)
331	5	04/26/88	Delegation of IDE Actions (Blue Book Memo #88-1)
333	2	03/31/88	PMA Review Schedules (Blue Book Memo # P87-1)
334	4	01/10/97	ODE Guidance Memoranda Table of Contents (Blue Book #T95-2_
344	5	03/29/96	510(k) Quality Review Program (Blue Book Memo I96-1))
357	2	10/23/86	Sabbatical Program for ODE Reviewers (#A86-2)
360	6	01/29/93	Telephone Communications Between ODE Staff and Manufacturers (#I93-1)
361	6	02/12/90	510(k) Sterility Review Guidance; (#K90-1)
362	6	05/17/89	Review of IDEs for Feasibility Studies
365	1	10/25/89	Integrity of the Medical Device Review Process (#I89-1)
366	1	08/24/90	Assignment of Review Documents (#I90-2)
368	1	02/15/90	Policy Development and Review Procedures (#I90-1)
369	5	07/19/89	Training for ODE Reviewers (#A89-1)
376	1	05/15/87	ODE Regulatory Information for the Office of Compliance
3859	10	06/30/93	510(k) Refuse to Accept Policy
387	7	04/24/90	When PMA Supplements are Required (Blue Book Memo #90-1)
388	2	04/24/90	ODE Peer Review Promotion Process (Blue Book Memo #A90-2)
389	2	04/24/90	Approval of Speaking Engagements (Blue Book Memo #A90-1)
401	3	05/20/94	510(k) Refuse to Accept Procedures (Blue Book Memo #K94-1)
402	4	05/20/94	PMA Refuse to File Procedures (Blue Book Memo #P94-1)
403	11	07/08/94	Premarket Approval Application (PMA) Closure

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
404	3	05/20/94	PMA/510(k) Triage Review Procedures (Blue Book Memo #G94-1)
405	8	07/12/95	Goals and Initiatives for the IDE Program (Blue Book Memo #D95-1)
406	6	11/21/95	Blue Book Memo #K95-1 Cover Letter: 510(k) Requirement During Firm-Initiated Recalls - Attachment A : Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices
4106	6	10/31/95	IDE List; Attachment C to D95-2, HCFA Reimbursement Categorization Determinations for FDA Approved IDE's
412	4	09/26/90	Document Control Procedures (Blue Book Memo #I90-3)
414	13	03/08/91	Device Labeling Guidance (Blue Book Memo #G91-1)
443	3	05/03/91	Clinical Utility and Premarket Approval; (#P91-1)
444	4	05/03/91	Panel Review of Premarket Approval Applications; (#P91-2)
445	6	05/03/91	PMA Compliance Program; (#P91-3)
446	6	02/12/92	Document Review Processing; (#I91-1)
447	1	05/29/91	Integrity of Data and Information Submitted to ODE; (#I91-2)
4859	12	06/30/93	Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy
557	7	06/06/96	Document Review by the Office of the Chief Counsel (Blue Book Memo #G96-1)
5859	13	06/30/93	PMA Refuse to File Policy
587	5	03/05/92	Nondisclosure of Financially Sensitive Information (Blue Book Memo #I92-1)
599	12	06/06/96	ODE Standard Operating Procedures for the Development and Use of Guidance Documents (Blue Book Memo #G96-2)
622	7	03/05/92	Training of Supervisors (Blue Book Memo #A92-1)
806	5	08/09/96	Memorandum of Understanding Regarding Patient Labeling Review (Blue Book Memo G96-3)
872	3	07/15/96	Continued Access to Investigational Devices During PMA Preparation and Review
931	14	06/30/93	Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment And Allocating Review Resources (included with 926 - 930)

ODE\DCLD\ GUIDANCE

051	16	02/01/94	Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using IFA/IHA/RIA/ELISA
082	16	08/12/91	Review Criteria for Blood Culture Systems
083	1	02/24/97	Review Criteria for Assessment of Serological In Vitro

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Diagnostic Devices for Detection of Serum Antibodies to Borrelia Burgdorferi [Lyme Disease]
095	10	09/26/94	Points to Consider for Collection of Data in Support of In Vitro Device Submissions for 510(k) Clearance
113	2	10/09/96	FDA Interim Policy on "Parents Access to Tests for Drugs of Abuse & 10/9/96 cover memo from JFStigi
152	24	08/31/95	Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies
165	14	02/21/97	Review Criteria for Assessment of Rheumatoid Factor In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay, Enzyme Linked Immunosorbent Assay , Particle Agglutination Test and Laser and Rate Nephelometry
272	14	10/01/88	Assessing the Safety/Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Points to Consider Regarding Labeling and Premarket Submissions
285	44	08/02/94	Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use
339	2	02/28/89	Premarket Notification - Consistency of Reviews
364	46	04/17/95	Draft Guidance for Submission of Immunohistochemistry Applications to FDA/ cover letter
417	15	07/15/91	Review Criteria for Assessment of Cytogenic Analysis Using Automated and Semi-Automated Chromosome Analyzers
459	34	07/15/94	Review Criteria for Assessment of Alpha-Fetoprotein (AFP) In Vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies
475	8	09/26/91	Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping Monoclonal Antibodies
494	8	10/17/91	Certification Program for In Vitro Diagnostic Devices Labeled "For Investigational Use Only"
518	12	11/21/91	Review Criteria for Assessment of Hepatitis A Virus Total & IgM Antibody - In Vitro Diagnostic Devices
527	15	08/01/92	Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents
553	6	02/01/96	Cover Letter/Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices
564	17	01/24/92	Guidance Criteria for Cyclosporine PMAs
588	13	09/17/92	Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter pylori
592	14	09/27/95	Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)
603	23	09/10/92	Draft: Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA) with Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor
604	15	02/14/96	Review Criteria for Assessment of Portable Blood Glucose Monitoring InVitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology
605	26	07/14/95	Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physician's Office Laboratory, and Home Use
629	10	05/31/90	Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases
631	26	05/31/91	Review Criteria for Assessment of Antimicrobial Susceptibility Devices
658	18	09/30/91	Draft Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin
665	36	05/12/92	Draft Document entitled Proposed Format: Package Insert for Immunohistochemistry Products
770	13	05/15/92	Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19
772	17	09/26/96	Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests
778	17	01/01/92	Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimen
800	19	03/02/93	Review Criteria for Assessment of Allergen-Specific Immunoglobulin E (IEG) In Vitro Diagnostic Devices Using Immunological Test Methodologies
848	21	09/01/92	Review Criteria for Assessment of Anti-Nuclear Antibodies (ANA) In Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD), and Enzyme Linked Immunosorbant Assay (ELISA)
927	18	05/31/96	DCLD Tier Categorizations; Triage Lists (includes 931)
950	7	11/13/95	Draft Data Required for Commericalization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers
957	22	09/19/96	Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification, [510(k)], to FDA
968	17	07/25/94	Points to Consider for Cervical Cytology Devices

ODE\DCRND\ GUIDANCE

037	12	02/21/96	Draft Guidance for Format and Content for Premarket Notification [510(k)] and DCRND Screening Checklist
054	5	06/26/90	Guide for 510(k) Review of Processed Human Dura Mater
124	11		Protocol for Dermal Toxicity Testing for Devices in Contact with

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Skin (Draft)
141	2	08/08/91	Automated Defibrillators: Operator's Shift Checklist and Manual
			Defibrillators: Operator's Shift Checklist
143	6	08/01/94	Draft Version 1 - Biofeedback Devices/Draft Guidance for 510k Content
1965	2	01/11/96	Tables for Draft Guidance for Implantable Cardioverter-Defibrillators
207	2	06/01/94	Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators
208	5	08/10/92	Draft Version -- Guide for Cortical Electrode 510(k) Content
209	8	08/20/92	Draft Version -- Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators
212	8	07/13/94	Draft Version -- Cranial Perforator Guidance
214	10	07/07/94	Draft Version -- Neuro Endoscope Guidance
215	6	08/23/94	Galvanic Skin Response Measurement Devices -- Draft Guidance for 510(k) Content
224	35	06/21/91	Draft Guidance: Human Heart Valve Allografts
300	6	08/01/94	Guide for TENS 510(k) Content (draft)
347	15	06/06/88	Premarket Notification [510(k)] Guide for Breathing Frequency Monitors (Apnea Monitors)
370	10	01/01/89	Balloon Valvuloplasty Guidance for the Submission of an IDE Application and a PMA Application
372	6	06/13/96	Implantable Pacemaker Lead Testing Guidance for the Submission of a Section 510(k) Notification
377	5	03/01/83	Guidance for Safety and Effectiveness Data Required in Premarket Notification (510k) Applications for Blood Oxygenators
381	9	01/01/90	Guidelines for Submitting Data In Support of Premarket Notification [510(k)] Application for Arrhythmia Detectors
382	3	01/24/89	Determining Equivalence of Intraaortic Balloon Catheters Under the 510(k) Regulation
383	9	09/26/96	Implantable Pacemaker Testing Guidance
385	67	10/01/89	Second Draft Proposed Standard for the Infant Apnea Monitor
391	23	05/11/90	Guidance: Vascular Graft Manufacturer, Developer, or Representative (Letter)
500	30	07/01/95	Draft Reviewer Guidance for Ventilators
550	1		510(k) Reviewer Guidelines - Tracheostomy Tubes
582	4	04/01/90	Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses
583	2	02/01/89	Guidance for Oxygen Conserving Device 510(k) Review 73 BZD

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			868.5905 Non-continuous Ventilator Class II
593	2		Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators
594	2		Review of 510(k) Notices for Carbon Dioxide Lasers for Neurosurgery
602	16	03/01/95	Electrode Recording Catheter Preliminary Guidance - Data to be Submitted to the FDA in Support of Premarket Notification
619	6	03/01/95	Draft Version Cardiac Ablation Preliminary Guidance - Data to be Submitted to the FDA in Support of Investigational Device Exemption Applications
627	5	09/12/94	Draft Version - Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3 - Implant Model
638	18	11/01/93	Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch
640	15	05/12/88	Guidance for Studies for Pain Therapy Devices -General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices
646	28	09/01/93	Rationale For Requirements Infant Apnea Monitor Standard
653	44	09/01/93	Recommended Test Methods Infant Apnea Monitor Standard
654	11	09/01/93	Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields - Infant Apnea Monitor Standard
763	4	03/01/94	Draft 510(k) Checklist for Sterilization Wraps
764	2	11/24/94	Draft of 510(k) Checklist for Through-Put Process Indicators
780	3	08/30/91	Heated Humidifier Review Guidance
781	1	08/30/91	Reviewer's Guidance Oxygen Concentrator
783	2	05/15/91	Catheter Guidance
784	5	11/09/90	Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators
846	67	05/13/93	Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices - PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents
873	4	07/12/93	Draft Battery Guidelines
885	79	08/01/93	Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses and Cover Letter
926	19	01/27/94	DCRND Triage Lists (includes 931)
946	14	10/25/95	Draft of Guidance Document for Testing of Orthopedic Implants With Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveillance
955	21	05/24/96	Draft Intravascular Brachytherapy - Guidance for Data to be Submitted to the FDA in Support of Investigational Device Exemption (IDE) Applications

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
965	44	01/11/96	Draft Guidance for Implantable Cardioverter-Defibrillators
985	8	04/14/93	Draft Emergency Resuscitator Guidance
996	1	03/16/94	Draft Reviewer Guidance on Face Masks and Shields for CPR
997	7	09/07/92	General Guidance Document Device: Non-Invasive Pulse Oximeter
998	27		Guidance for Labeling of Peak Flow Meters for Over the Counter Sale
999	1	07/24/96	DRAFT 510(k) Submission Requirements for Peak Flow Meters which supplement the Draft Reviewer Guidance for Premarket Notification Submissions

ODE\DDIGD Guidance Documents

047	1	02/20/97	510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants
1198	7	11/01/96	Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities (see 198)
198	29	04/26/96	Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (see 1198)
948	6	12/09/96	Information Necessary For Premarket Notification Submissions For Screw-Type Endosseous Implants

ODE\DGRD\ GUIDANCE

028	7		Guidance for the preparation of Premarket Notification [510(k)] for Resorbable Periodontal Barriers
033	13	02/21/97	Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants
085	19	01/23/95	Guidance Document for the Preparation of Premarket Notification 510(k) for Temporomandibular Joint Implants
086	7		Overview of Information Necessary for Premarket Notification Submission for Endosseous Implants
087	6		Outline of Recommended Procedures for a Clinical Investigation of Endosseous Implants Under a 510(k)
088	4		Outline of Recommended Procedures for Animal Laboratory Studies of Endosseous Implants
090	3	07/06/93	510(k) Information Needed for Hydroxyapatite Coated Titanium Endosseous Implants
091	3	07/13/93	510(k) Information Needed for Ti-Powder Coated Titanium Endosseous Implants
092	2	08/12/93	510(k) Information Needed for Metallurgical Endosseous Implants

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
107	3	02/12/96	Letter: Core Study for Silicone Breast Implants
133	11	08/20/93	Device Considerations for Spinal Fixation Device Systems
144	29	05/11/92	Draft Guidance for Preparation of FDA Submissions of Silicone Gel-Filled Breast Prostheses
145	3	09/01/94	Draft 510(k) Checklist for Air Cleaners/Air Purifiers
146	11	09/01/94	Draft Guidance for Testing of Alternative Breast Prostheses (nonsilicone gel-filled)
163	2	05/03/95	Clarification on Cleaning Agents and General Purpose Disinfectants that Require a 510(k) Submission
180	4	03/28/95	Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices
1833	3	09/19/95	Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities
187	15	08/01/95	Draft Guidance Document for Femoral Stem Prostheses
1993	6	03/20/96	Graphs and figures for Patient Restraint Guidance Document
233	64	02/18/93	Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament
234	29	08/12/88	Guidance Document for the Preparation of IDE and PMA Applications for Bone Growth Stimulator Devices
252	12	04/01/93	Guidance Document for Testing Biodegradable Fracture Fixation Implant Devices
274	2	07/11/85	Electrical Muscle Stimulator (EMS) Labeling Indications; Contraindications; Warnings; etc.
307	14	07/26/95	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Submerged (Underwater) Exercise Equipment
314	2		Inclusion of Class II or Class III Type Devices in Surgical Kits Under 510(k) - (sutures)
315	4	03/11/86	Establishment of ODE Policy for Labeling Surgical Suture Size
325	11	07/26/95	Guidance Document for the Preparation of Premarket Notification [510(K)] Applications for Electromyograph Needle Electrodes
346	9	07/26/95	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles
350	15	07/05/96	Guidance Document for the Preparation of Premarket Notifications [510(k)] Applications for Powered Muscle Stimulators, and Ultrasound Diathermy and Muscle Stimulators
353	23	05/16/89	Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Endosseous Implant for

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Prosthetic Attachment
354	9	01/01/92	Technological Reporting for Powered Muscle Stimulator 510(k) (EMS)
355	9	01/10/95	Guidance Document for the Preparation of Premarket Notification for 510(k) for Ceramic Ball Hip Systems
386	27	06/01/95	Guidance on the Content and Organization of a Premarket Notification for a Medical Laser
392	26	10/01/90	Guidance on 510(k) Submission for Implanted Infusion Ports
424	22	11/18/86	Guidelines for the Premarket Testing and Labeling of Antimicrobial Agents for Medical Devices
450	16	04/01/93	Guidance on the Content of Premarket Notification [510(k)] Submissions for Hypodermic Single Lumen Needles
453	16	05/01/95	Guidance Document for Testing Acetabular Cup Prostheses
532	47	01/18/95	Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses
556	11	07/01/95	Guidance Document on Dental Handpieces
576	42	12/06/96	Guidance on the Content and Format of Premarket Notification {510(k)} Submissions for Liquid Chemical Germicides
636	7	01/09/97	Draft Guideline for Reviewing Spinal Fixation Device Systems
642	19	01/01/96	Guidance for the Preparation of A Premarket Notification 510(k) for Direct Filling Dental Composites
668	5	11/01/93	Draft Outline for a Guidance Document for Testing Orthopedic Bone Cement
689	13	07/26/95	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Beds
729	13	07/26/95	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Immersion Hydrobaths
735	13	07/26/95	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables
762	14	07/26/95	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems
790	10	08/11/92	510(k) Guidance for Screw Type Endosseous Implant for Prosthetic Attachment
817	14	03/31/95	Checklists for Wound Dressing 510(k)/Interactive Wound and Burn Dressing IDE Submission
818	11	07/26/95	Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Therapeutic Massagers and Vibrators

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
821	21	04/01/93	Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes
822	18	03/01/93	Guidance on the Content of Premarket Notification [510(k)] Submissions for Clinical Electronic Thermometers
823	19	03/01/93	Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps
824	26	03/16/95	Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters
827	8	04/28/94	Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement
828	11	07/26/95	Guidance document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices
829	16	02/21/97	Reviewers Guidance Checklist for Orthopedic External Fixation Devices
830	9	04/01/93	Draft Guidance for the Preparation of Premarket Notification [510(k)] for Cemented Semi-Constrained Knee
832	7	09/05/96	Draft Guidance Document for the Preparation of Premarket Notification 510(k) Applications for Orthopedic Devices - The Basic Elements
833	34	03/01/93	Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities
881	23	08/01/93	Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities
888	19	08/01/93	Draft Guidance on Premarket Notifications [510(k)] Submissions for Surgical Gowns and Surgical Drapes
891	13	02/11/97	Guidance on the Content and Format of Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices
895	8	10/01/93	Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers
902	21	10/01/93	Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants
904	19	05/10/95	Draft 510(k) Guideline for General Surgical Electrosurgical Devices
909	7	05/01/94	Draft Guidance for Arthroscope and Accessory 510(k)s
914	13	04/20/96	Guidance Document for Testing Biodegradable Polymer Fracture Fixation Devices
915	8	04/20/96	Guidance Document for Testing Bone Anchor Devices
916	8	05/01/95	Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
929	23	01/27/94	DGRD Tier Categorization; Triage Lists (includes 931)
934	34	03/01/95	Draft Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features
956	12	02/21/97	Reviewers Guidance Checklist for Intramedullary Rods
984	3	07/01/93	Draft Guidance document for the Preparation of Premarket Notification [510(k)'s] for Dental Casting Alloys
993	1	03/29/96	Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints

ODE\DOD\ GUIDANCE

055	13	06/13/95	Guidance Document Multifocal Intraocular Lens IDEs: Preclinical and Clinical Use
079	2	09/16/87	Labeling Suggestions for Ultraviolet (UV) Light Absorbing Contact Lenses
093	2	10/30/96	Announcement: Information for Manufacturers and Users of Lasers for Refractive Surgery
1073	12	07/26/96	Eye Valve Implants (and all Glaucoma Drainage Devices) Manufacturer letter
1093	3	10/25/96	Letter to Manufacturers and Users of Lasers for Refractive Surgery
2093	33	10/25/96	Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers
256	46	08/06/81	Suggestions Contact Lens Product Labeling (Draft)
275	70	07/15/85	Testing Guidance/Guidelines for Class III Soft Hydrophilic Contact Lens Solutions (Draft)
309	14	05/22/86	Safety and Labeling Requirements for Heat Disinfection Units used with soft contact lenses
3093	1	10/25/96	Announcement by Dr. Alpert at 7/26/96 Ophthalmic Panel Meeting concerning Manufacturers and Users of Lasers for Refractive Surgery
310	12	05/16/86	IOL: Ultraviolet (UV) Absorbing Lens Labeling/Trade Names/Report Requir. for Ant. Chamber Lenses/Submission of Manufact. Inform. for PMAs; UV-Absorbing IOL PMAs
312	9	07/29/85	Annual Reports in Place of PMA Supplements for Contact Lens
319	3	11/18/86	New Procedures for Implementing Changes in Contact Lens Packaging Materials
320	3	11/18/86	New Procedures for Implementing Changes in Contact Lens Solution Packaging Materials
321	8	12/18/86	New Requirements for Investigations of Anterior Chamber Intraocular Lenses (IOL)

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
322	3	01/18/90	Adverse Reaction Reporting Requirements; Applicable to IOLs Investigations
394	2	10/01/81	IOL Guidance for Submitting Sterilant Residue Data for PMA's (Letter)
395	13	11/09/81	IOL Guidance for Types of Information Necessary When Submitting Summary of Safety and Effectiveness Data (Letter)
396	4	03/13/85	IOL: How Labeling Modification Should be Submitted to the FDA (Letter)
397	3	03/11/85	Waivers from Certain Requirements of the IOL Regulations
4093	3	10/25/96	Owners Certification of Lasers as PMA Approved Devices
5093	1	10/25/96	Announcement: Training Sessions for Manufacturers & Users of Lasers for Refractive Surgery
514	113	06/12/95	Proposed Draft Guidance for Photorefractive Keratectomy Laser Systems: IDE Studies and PMA Applications
6093	2	10/25/96	Update on Excimer Lasers for Nearsightedness, T96-36
767	10	01/06/95	Guidance Document Approval Requirements for IOLs with an Extended Power Range
795	39	06/09/80	Guidelines for Intraocular Devices
943	8	03/08/94	Letter: All Contract Lens Manufacturers and Other Interested Persons: Procedures for Adding the Monovision Fitting Technique to the Labeling of Class III Single Vision Contact Lenses for Managing Presbyopia

ODE\DRAERD\GUIDANCE

096	5	06/07/94	Guidance for the Content of Premarket Notifications for Urine Drainage Bags
097	11	09/12/94	Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters
098	5	11/01/94	Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology
099	3	11/23/94	Draft - 510(k) Checklist for Conditioned Response Enuresis Alarms
100	4	11/30/94	Draft Guidance Outline - Points to Consider for Clinical Studies for Vasovasostomy Devices
134	4	07/12/94	Gastroenterology and Urology Device Tier Designations
161	38	05/01/95	Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter)
162	14	03/17/95	Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology
1634	7	10/31/96	Tables and Graphs for: Manufacturers & Distributors of Diagnostic Ultrasound Equipment, Accessories, & Related

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Measurement Devices
166	28	05/25/95	Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons
177	14	05/30/95	Draft Guidance for the Content of Premarket Notifications for Penile Rigidity Implants
189	11	06/06/95	Draft 510(k) Checklist for Non-implanted Electrical Stimulators used for the treatment of Urinary Incontinence
190	7	06/22/95	Draft 510(k) Checklist for Endoscopic Light Sources used in Gastroenterology and Urology
1907	23	03/27/96	Hysteroscopes & Gynecologic Laparoscopes: Submission Guidance for a 510(k)
192	6	05/25/95	SE Comparison Chart for Laparoscopes
202	2		Guidance to Manufacturers on the Development of Required Postapproval Epidemiologic Study Protocols for Testicular Implants
232	6		Guidance/Guidelines for Evaluation of Laparoscopic Bipolar/Thermal Coagulator (and Accessories)
244	4	03/08/77	Guidance (Guidelines) for Evaluation of Fetal Clip Electrodes
245	7	11/22/77	Guidance (Guidelines) for Evaluation of Tubal Occlusion Devices
248	9	05/10/78	Guidance (Guidelines) for Evaluation of Hysteroscopic Sterilization Devices
281	93	12/01/85	510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices
2907	7	10/10/95	510(k) Guidance for 2-D Laparoscope: SE Comparison Chart
327	24	05/01/90	Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Children Ages 2 through to 17 Years
335	8	11/24/87	Necessary Information for Diagnostic Ultrasound 510(k) - Draft
340	122	08/02/88	Guidance for Content and Review of a Magnetic Resonance Diagnostic Device 510(k) Application
358	33	01/19/89	Doppler Ultrasound Instrumentation; FDA 510(k) Guidance for the Preclinical Demonstration and Comparison of Effectiveness
384	16	04/04/90	Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Disease
3907	20	10/10/95	Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)
398	44	04/13/95	Condom Package
416	9	08/01/93	Guidance for the Comment and Review of 510(k) Notification for Picture Archiving and Communications Systems
418	14	01/18/91	Draft of Suggested Information for Reporting Extracorporeal

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
421	16	03/01/82	Shock Wave Lithotripsy Device Shock Wave Guidelines for Premarket Testing of New Conventional Hemodialyzers, High Permeability Hemodialyzers and Hemofilters
431	6	02/10/93	Guidance for the Content of Premarket Notifications for Ureteral Stents
455	27	09/24/96	Testing Guidance for Male Condoms Made from New Material (Non-Latex)
464	14	04/01/91	Guidance for Submission of a 510(k) for an Air Conduction Hearing Aid
482	8	02/10/93	Guidance for the Content of Premarket Notifications for Biopsy Devices used in Gastroenterology and Urology
490	10	07/29/94	Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems
515	7	08/01/95	Draft 510(k) Checklist for Urological Irrigation System and Tubing Set
533	16	11/11/94	Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)
547	22	03/14/96	Draft Thermal Endometrial Ablation Devices: Submission Guidance for an IDE
567	11	01/24/92	Draft Guidance for the Content of Premarket Notification for Urological Balloon Dilation Catheters
577	26	05/01/90	Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Adults at Least 18 Years of Age
621	12	11/20/92	Premarket Testing Guidelines for Falloposcopes
634	63	02/17/93	Diagnostic Ultrasound 510(k) Guidance
641	16	09/28/76	Guidelines for Evaluation of Non-Drug IUDs
657	11	08/05/94	Cover Letter/Draft Guidance to Hearing Aid Manufacturers for Substantiation of Claims
667	4	08/30/94	Draft Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices (ELD)
768	7	08/16/95	Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology
788	2	02/01/90	Reviewer Guidance for Automatic X-Ray Film Processor 510(k)
791	3	04/01/90	Guidance for the Technical Content of a Premarket Approval (PMA) Application for an Endolymphatic Shunt Tube with Valve
809	51	03/16/93	Draft Guidance for Preparation of PMA Application for Testicular Prostheses
810	55	03/16/93	Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
820	50	03/31/93	Premarket Testing Guidelines for Home Uterine Activity Monitors
842	11	04/13/95	Draft Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis
850	21	11/29/95	Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence
864	13	02/05/92	Draft Guidance for Information on Clinical Safety and Effectiveness Data for Extracorporeal Shock Wave Lithotripsy of Upper Urinary Tract (Renal Pelvis, Renal Calyx and Upper Ureteral) Calculi
866	26	11/09/92	Draft Guidance for Review of Bone Densitometer 510(k) Submissions
870	21	03/14/95	Draft Guidance for the Content of Premarket Notifications - DRAERD Screening Checklist
892	3	09/19/94	Draft 510(k) Checklist for Sterile Lubricating Jelly Used with Transurethral Surgical Instruments
928	14	01/27/94	DRAERD Tier Categorizations; Triage Lists (includes 931)
932	13	12/15/93	DRAERD Triage Pilot Program, Description
954	14	10/21/96	Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims
981	17	06/19/96	Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems
991	3	02/23/95	510(k) Checklist for Condom Catheters
992	14	03/21/95	Draft Guidance for the Content of Premarket Notifications for External Penile Rigidity Devices

ODE\OTHER\ GUIDANCE

015	51	08/01/86	An Introduction to Transcutaneous Electrical Nerve Stimulation: TENS
016	25	01/01/96	A Small Business Guide to FDA
023	18	09/01/87	Impact Resistant Lenses: Questions and Answers (Including Certification Statement)
067	2	11/17/95	Five Videos on Hemodialysis
078	10		Perspectives on Clinical Studies for Medical Device Submissions (Statistical)
084	2		PMA Review Statistical Checklist
147	18	01/19/95	Premarket Submission Cover Sheet: Instructions, and Survey
150	19	05/26/95	Information on FDA's Proposed Pilot of Third Party Review of Medical Device 510(k)s

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
1616	4	09/17/96	PJPhillips cover letter - ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software - Draft Document (pages 1-4)
223	3	03/22/91	Latex Bibliography
225	10	06/16/78	Methods for Conducting Recall Effectiveness Checks
226	2	09/08/95	Medical Device Reporting (MDR)
227	37	09/01/93	Human Factors Principles for Medical Device Labeling
228	2	04/01/93	Suggestions for Submitting Premarket Approval (PMA) Application
236	5	08/01/95	Abbreviated Reports on Radiation Safety for Microwave Product (Other than Microwave Ovens) E.G. Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security Systems
247	27	02/21/96	Application of the Medical Device GMPs to Computerized Devices and ManufacturingProcesses Medical Device Guidance for FDA Investigators
2616	20	09/17/96	ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software - Draft Document (pages 5-24)
267	14	12/01/83	Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Device
268	10	02/01/89	Color Additive Status List (Inspection Operations Manual)
269	64	06/01/84	Points to Consider inthe Characterization of Cell Line Used to Produce Biological Products
283	4	01/01/86	FDA Guide for Validation of Biological Indicator Incubation Time
284	4	01/01/86	Biotechnology and FDA Regulation of Hybridoma In Vitro Diagnostic Products: List of Current Devices and Guidelines for Manufacturers
286	24	03/01/88	Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Ovens Compliance Survery Instruments
287	10	10/01/95	Guidance on Significant and Nonsignificant Risk Device Studies
288	54	05/01/89	FDA Clinical Investigator Information Sheets
295	25	09/01/89	Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers FDA 90-4236
296	2	06/01/87	Color Additive Petitions
2994	41	10/09/96	Design Control Guidance for Medical Device Manufacturers
2995	39	10/09/96	Do It By Design: An Introduction to Human Factors in Medical Devices

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
311	1		Suggested Format for IDE Progress Reports
329	4	03/27/87	Industry Representative on Scientific Panels
337	43	08/29/91	Draft Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(K) Review
338	7	06/01/87	Master Files: Part III; Guidance on Scientific and Technical Information
351	3	11/13/89	FDA Policy for the Regulation of Computer Products
352	8	01/01/90	Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976
3616	20	09/17/96	ODE Guidance for the Content of Premarket Submissions for Medical Devices Containing Software - Draft Document (pages 25-44)
363	4	08/09/89	Toxicology Risk Assessment Committee
367	3	11/20/89	Meetings with the Regulated Industry (#189-3)
371	2	10/01/91	4-Of-a-Kind PMAs
390	5	01/01/90	Substantial Equivalence (SE) Decision Making Documentation
415	26	03/01/91	Shelf life of Medical Devices
420	22	11/01/80	Product Development Protocol Guideline (PDP)
423	4	11/01/85	Guideline for Preparing Notices of Availability of Investigational Medical Devices
425	13	05/01/87	Guideline on General Principles of Process Validation
4258	12	07/30/96	Third Parties Recognized to Review Selected Premarket Notifications During FDA's Two-year Pilot Program
426	44	06/01/87	Guideline on Sterile Drug Products Produced by Aseptic Processing
427	44	12/01/87	Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-product Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices
428	9	01/01/88	Guideline for the Monitoring of Clinical Investigations
448	12	08/01/92	Guidance for Preparation of PMA Manufacturing Information
4616	20	09/17/96	ODE Guidance for the Content of Premarket Submissions for Medical Devices Containing Software - Draft Document (pages 45-64)
476	36	01/01/96	Clinical Trial Guidance for Non-Diagnostic Medical Devices
491	5	03/11/88	Condoms for Prevention of Sexually Transmitted Diseases
497	14	11/08/91	Guidance to Manufacturers on the Development of Required Postmarket Surveillance Study Protocols Under Section 522 (a)(1) of the Federal Food, Drug and Cosmetic Act
521	12	10/31/91	Intercenter Agreement Between The Center for Biologics Evaluation and Research and The Center for Devices and

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)			
Shelf_#	Pages	Doc._Date	Title
			Radiological Health
524	14	10/31/91	Intercenter Agreement Between The Center for Drug Evaluation and Research and The Center for Devices and Radiological Health
537	20	06/01/84	Statistical Aspects of Submissions to FDA: A Medical Device Perspective
5616	21	09/17/96	ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software - Draft Document (pages 65-85)
575	26	11/15/95	Color Additive for Medical Devices
584	13	03/11/92	Preamendments Class III Devices
596	3	03/14/95	Premarket Notification Truthful and Accurate Statement (As Required by 21 CFR 807.87(j))
597	2	03/14/95	Premarket Notification Class III Certification and Summary (As Required by 21 CFR 807.94)
598	2	03/14/95	Premarket Notification 510(k) Statement (As Required by 21 CFR 807.93)
607	27	08/26/91	Device, Drug or Cosmetic
609	11		Guidance for Submitting Reclassification Petition
613	6	03/07/94	Automatic Detention of Medical Devices
616	1	09/18/96	Obtaining "ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software - Draft Document" from CDRH
635	7	10/25/96	Draft Immunotoxicity Testing Framework
671	5	09/01/89	List of Contract Sterilizers
789	3	11/19/93	Classified Convenience Kits
797	1	02/27/96	Suggested Content for Original IDE Application Cover Letter
814	4	12/03/92	Certified Color Manufacturers - List of Manufacturers Names and Addresses From 1990 to Present
815	8	05/11/93	Device Specific Guidance Documents
858	1	12/20/95	Premarket Notification [510(k)] Status Request Form
879	2	04/24/96	Indication for Use Statement / Change in 510(k) Format
935	42	01/10/97	Deciding When to Submit a 510(k) for Change to an Existing Device (includes 936)
936	5	08/14/95	Attachments to #935: Deciding When to Submit . . . (included with 935)
937	5	01/14/97	Premarket Approval Applications; Most Recent Monthly Update
939	17	11/12/96	Medical Device Exemptions List
944	6	07/12/96	Testing for the Sensitizing Chemicals in Latex Medical Devices - Proposed Modified Guidance
949	9	03/14/97	Draft Design Control Inspectional Strategy

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
958	17	05/22/96	Draft Guidance for Testing MR Interaction with Aneurysm Clips
964	3	02/12/96	Coronary and Cerebrovascular Guidewire Guidance
994	49	03/14/97	Design Control Guidance for Medical Device Manufacturers
995	56	03/04/97	Do it By Design - An Introduction to Human Factors in Medical Devices

OTHER INSTRUCTIONS

294	1	02/21/96	RAPS Electronic Media Services/RAPS Fax-on-Demand Hotliine
520	1	11/01/91	How to Make A Freedom of Information (FOI) Act Request to FDA

POSTMARKET SURVEILLANCE\OTHER

206	16	06/06/93	Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)
341	3	12/12/95	FDA/CPSC Public Health Advisory: Hazards Associated with the Use of Electric Heating Pads
422	13	03/01/84	Medical Device Notification and Voluntary Safety Alert Guideline
463	2	03/29/91	FDA Medical Alert - Allergic Reactions to Latex-Containing Medical Devices

PUBLIC INFORMATION\OTHER

429	4	04/21/92	Important Information on Shiley C-C Valve Fractures
438	8	01/01/90	Condoms and Sexually Transmitted Diseases ... Especially AIDS
439	4	01/01/90	Visitors Guide to CDRH Buildings/Twinbrook, Chapman, Wilkins, Piccard
440	4	01/01/90	AIDS - Information for the Dialysis Health Professional
441	4	01/01/90	AIDS - Information for the Dialysis Patient
442	2		It's Not Only A Good Idea - It's Also The Law
488	4	04/01/91	FDA Consumer Magazine: Contact Lenses: The Better the Care the Safer the Wear
504	24	12/01/90	Medications that Increase Sensitivity to Light: 1 1990 Listing
506	4	06/01/89	FDA Consumer Magazine: Healthy Tan' - A Fast Fading Myth
541	10	01/06/91	HHS News Release on Breast Implants with Attachments - Statement on Silicone Gel Breast Implants, FDA Medical Alert: FDA Request Moratorium on Silicone Breast Implants, FDA Backgrounder: Important Information on Breast Implants
561	4	05/01/83	FDA Consumer: EMS Fraudulent Flab Remover
569	8	02/01/86	FDA Consumer: Do-It-Yourself Medical Testing

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
572	4	03/01/87	FDA Consumer: A Complaint Department for Medical Devices
578	4	05/01/86	FDA Consumer: The Medical Device Amendments: 10 Years After
579	2	01/01/89	Yorick The CDRH Bionic Skeleton
581	8	04/01/89	FDA Consumer: A Primer on Medical Imaging - Part One
590	2	07/20/92	Update on Possible Hazards of Traffic Radar Devices
643	4	04/20/95	Information for Women Considering Saline-Filled Breast Implants
942	1	09/28/94	FDA Fact Sheet Mammography Quality Standard Act
RADIOLOGICAL HEALTH - LASERS			
230	6	09/14/95	Letter to Manufacturers and Importers: Lasers and Laser Products
251	22	09/01/95	Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) FDA 95-8140
264	12	09/01/95	Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products
277	33	09/01/95	Guide for Preparing Product Reports for Lasers and Products Containing Lasers
595	19		Viable Bacteriophage in CO2 Laser Plume: Aerodynamic Size Distribution
620	1		Review of "YAG" Lasers for Neurosurgery
RADIOLOGICAL HEALTH - MICROWAVE			
239	67	03/01/85	Guide for Preparing Reports on Radiation Safety of Microwave Ovens
RADIOLOGICAL HEALTH - NON-IONIZING			
1081	4	08/29/96	Keeping Medical Devices Safe From Electromagnetic Interference
1082	6	08/29/96	Medical Devices and EMI: The FDA Perspective
1083	2	08/29/96	Update on Cellular Phone Interference with Cardiac Pacemakers
1084	4	08/29/96	Radio Waves May Interfere with Control of Powered Wheelchairs and Motorized Scooters
1085	3	08/29/96	Why Does the FDA Concern Itself with ESD?
1086	14	08/29/96	Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations
1087	4	10/24/96	Letter to: Registered Medical Device Manufacturers, Firms Filing Electronic Product Radiation Reports, Related Trade and Professional Associations
240	9	04/30/74	Guide for Submission of Information on Analytical X-Ray

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
241	28	02/01/75	Equipment Required Pursuant to 21 CFR 1002.10 Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40
RADIOLOGICAL HEALTH - OTHER			
036	71	04/01/91	1990 Annual Report on the Administration of the Radiation Control for Health and Safety Act of 1968 Public Law 90-602
1040	17	09/19/95	Records and Reports Regulations for Radiation Emmitting Electronic Products
231	15	05/28/81	Letter: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist
242	17	04/01/89	Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12)
243	11	10/01/87	Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)
254	10	11/01/80	Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12
263	8	09/01/95	Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps
566	2	01/01/85	Reducing Patient Exposure During Scoliosis Radiography
RADIOLOGICAL HEALTH - SUNLAMPS			
229	1	09/14/95	Letter to Manufacturers and Imports: Sunlamp Porudcts, Ultraviolet Lamps and Associated Equipment
262	10	09/01/95	Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products
270	36	03/01/88	Quality Control Guide for Sunlamp Products
279	27	09/01/95	Guide for Preparing Initial Reports and Model Change Reports on Sunlamps and Sunlamp Products (21 CFR 1002)
348	23	11/16/95	Reporting Guide for Initial Reports and Model Change Reports on High Intensity Mercury Vapor Discharge Lamps
RADIOLOGICAL HEALTH - TELEVISION			
259	29	08/25/94	T.V. Standards Information for: Television Receivers /Products with Liquid Crystal Displays; Import. of Noncompl. Televisions/Exempt. from Reporting/Recordkeeping
260	71	11/29/95	Reporting and Compliance Guide for Television Products Including Product Report (21 CFR 1002.10) Supplemental Report (21 CFR 1002.11) Radiation Safety Abbreviated Report

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
			(21 CFR 1002.12) Annual Report (21 CFR 1002.13) Information and Guidance

RADIOLOGICAL HEALTH - ULTRASONIC

951	5	08/01/95	Abbreviated Reports on Safety of Non-Medical Ultrasonic Products
-----	---	----------	--

REGULATIONS\CFR PARTS

1041	19	09/21/95	21 CFR Part 50, et al. Protection of Human Subjects; Informed Consent; Proposed Rule
1051	12	07/30/96	Testing for the Sensitizing Chemicals in Latex Medical Devices and Federal Register Notice: FR 21 CFR Part 801; Latex-containing Devices; User Labeling; Proposed Rule
1088	19	11/20/96	21 CFR Part 810 - Medical Device Recall Authority; Final Rule
1090	5	03/20/97	21 CFR Parts 803 and 804; Medical Devices; Medical Devices Reporting; Annual Certification; Final Rule
1336	3	04/11/96	Federal Register: Extension of Effective Date: Medical Device; Medical Device User Facility and Manufacturer Reporting, Certification and Registration; Office of Management and Budget Approval; Final rule
238	3	01/28/97	Emergency Informed Consent Exception, 21 CFR 50.24

REGULATIONS\FOREIGN

006	41	01/01/95	The Medical Device Amendments of 1976, as Further Amended by the Safe Medical Devices Act of 1990
018	6		An Introduction to Medical Device Regulations
027	81	10/05/90	House of Representatives Report 101-808 Safe Medical Devices Act of 1990
029	7		Device User Facility Reporting Sections of the Safe Medical Devices Act of 1990 (Public Law 101-629)
183	37	04/01/95	Reinventing Drug & Medical Device Regulations
1990	126	01/26/96	Proposed Regulatory Requirements for Medical Devices Sold in Canada
205	107		FDA IRB Information Sheet
332	10	05/05/94	Citizen Petition - Points to Consider
430	2	01/01/76	30-Point Summary; Medical Device Amendments of 1976 (Public Law 94-295)
435	2	01/01/95	Need Help With Medical Device Regulations? Contact DSMA
505	16	10/27/92	Public Law 102-539 Mammography Quality Standards Act of 1992
610	52	12/01/95	U.S. Food and Drug Administration Regulation of Medical Devices (Background Information for Foreign Officials)

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_# Pages Doc._Date Title

REGULATIONS\OTHER

3258	31	08/16/96	List of Eligible Devices
393	16	01/01/81	Comparison of Drug and Device Good Manufacturing Practice Regulations
411	30	11/01/90	Suggested Changes to the Medical Device Good Manufacturing Practices Regulation
419	7	09/01/79	Petition Guidelines on Exemption or Variance from the Device GMP Regulation

REGULATIONS\UNCODIFIED

025	21	11/28/90	Safe Medical Devices Act of 1990, PL 101-629
1030	84	07/28/95	Proposed Reclassification & Exemption from Premarket Notification of Certain Medical Devices; Docket 95N-0139
1031	15	07/28/95	21 CFR Parts 862 and 872 - Medical Devices; Exemption from Premarket Notification for Certain Classified Medical Devices; Final Rule Docket 94M-0260
1032	10	07/28/95	21 CFR Part 866 - Immunology and Microbiology Devices: Revocation of the Exemption from Premarket Notification; Blood Culturing System Devices; Final Rule Docket 91N-0063
1033	6	07/28/95	21 CFR Part 862, 864, 866, 868, and 886 - Medical Devices; Withdrawal of Proposed Exemptions; Proposed Rule; Withdrawal; Docket 94M-0260
1258	9	04/03/96	FR Notice:Third Party Review of Selected Premarket Notification; Pilot Program
1303	7	07/01/95	FR Notice of Availability, Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule; July 1995
1981	5	09/04/96	Latex Containing Devices; User Labeling; Proposed Rule. Federal Register [Docket # 96N-0119]
2258	2	04/01/96	Third Party review of Selected Premarket Notifications [510(k)s]
2303	89	07/01/95	Preamble - Working Draft of the Current GMP Final Rule July 1995
282	3	03/28/97	Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation [docket # 90N-0172
3303	19	07/31/95	Regulation - Working Draft of the Current GMP Final Rule July 1995

SAFETY ALERTS

068	3	03/01/94	FDA Public Health Advisory: Avoiding Injuries from Rapid Drug or I.V. Fluid Administration Associated with I.V. Pumps and Rate Controller Devices
081	4	10/16/95	FDA Public Health Advisory: Retinal Photoc Injuries From

CDRH Facts-On-Demand DSMA Index

TOPIC (Category)

Shelf_#	Pages	Doc._Date	Title
			Operating Microscopes During Cataract Surgery
218	1	01/01/89	FDA Safety Alert: For Salt Tablet Users
219	4	02/16/90	FDA Safety Alert: Important Tips for Apnea Monitor Users
220	2	05/11/90	FDA Safety Alert: Gas/Air Embolism Associated with Intrauterine Laser Surgery
221	2	12/28/90	FDA Safety Alert: Serious Problems with Proplast - Coated TMJ Implant
222	2	08/28/90	FDA Safety Alert: Hepatitis B Transmission Via Spring-Loaded Lancet Devices
549	2	05/20/92	FDA Safety Alert: Aluminum and Other Trace Element Contamination in Dialysis Facilities
860	4	08/23/95	FDA Safety Alert: Entrapment Hazards with Hospital Bed Side Rails
982	3	06/26/96	FDA Public Health Advisory: Potential Risk of Spontaneous Combustion in Large Quantities of Patient Examination Gloves

VIDEO & TELECONFERENCES

975	42	04/15/96	Information Session for Prospective Third Parties
-----	----	----------	---